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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/088,866   | 07/02/2002  | Michael Schirner     | SCH 1869            | 6769             |
| 23599 7590 06/29/2009<br>MILLEN, WHITE, ZELANO & BRANIGAN, P.C.<br>2200 CLARENDON BLVD.<br>SUITE 1400<br>ARLINGTON, VA 22201 |             |                      |                     |                  |
| EXAMINER<br>HUFF, SHEELA JITENDRA  |             |                      |                     |                  |
| ART UNIT   |             | PAPER NUMBER         |                     |                  |
| 1643   |             |                      |                     |                  |
| NOTIFICATION DATE  |             | DELIVERY MODE        |                     |                  |
| 06/29/2009   |             | ELECTRONIC           |                     |                  |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

docketing@mwzb.com

### Office Action Summary

**Application No.**

10/088,866

**Applicant(s)**

SCHIRNER ET AL.

**Examiner**

Sheela J. Huff

**Art Unit**

1643

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 May 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 15-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 15-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SE-US)  
Paper No(s)/Mail Date 5/12/09: 10/15/08
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date: \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

***DETAILED ACTION***

***Response to Amendment***

The amendment filed on 5/12/09 has been considered. Applicant's arguments are deemed not to be persuasive.

Claims 15-37 are pending.

***Information Disclosure Statement***

The IDS filed 10/15/08 has been considered and an initialed copy of the PTO-1449 is enclosed.

The information disclosure statement filed 5/12/09 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the reference was not found.

***Response to Arguments***

***Claim Rejections - 35 USC § 112***

Claims 16, 18, 20, 22, 27-33 and 35 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 18, 20, 22 and 27-33 were inadvertently omitted from the previous office action. Claim 35 is added because of its recitation of L19. The reasons for this rejection are of record in the paper mailed 2/1/06.

Applicant has deposited L19. This deposit is incomplete because applicant did not provide the following assurances as required in 37 CFR 1.801-1.809. If the deposit is made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by applicant or assignees or a statement by an attorney of record who has authority and control over the conditions of deposit over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty and that all restrictions upon public access to the deposited material will be irrevocably removed upon the grant of a patent on this application. This requirement is necessary when deposits are made under the provisions of the Budapest Treaty as the Treaty leaves this specific matter to the discretion of each State.

Applicant did not address the rejection as it pertains to E1.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 15-33 and 36-37 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Neri et al Nature Biotechnology Vol. 15 p. 1271 (11/97) or Neri et al US 2003/0045681 (filed 5/11/98) in view of Viti et al Cancer Research vol. 59 p. 347 (1/99), applicant's admission in the sentence bridging pages 7-8 of the specification and Licha et al US 6083485 (filed 11/7/97). The reasons for this rejection are of record in the paper mailed 11/27/07.

Applicant provides another declaration which states that the "A" in the previous declaration is the same in conjugates 1 and 5 and is L19 in the previous declaration and that the "A in conjugates 2-4 is L19 linked to cis-Tag. The declaration also states that the cis Tag moiety "has no measurable effect on either the immunoreactivity or the fluorescent quantum yield". This statement is an assertion as there is no objective evidence to support this. In fact, applicant's next argument is that the immunoreactivity should remain the same in all 5 conjugates because the same antibody. As stated in the declaration filed 7/19/07, "The data demonstrate that the conjugates of the invention provide a significantly better immunoreactivity, which in practice leads to better tumor imaging efficacy, over the conjugate of Neri et al." Thus, it is applicant who, in the 7/19/07 declaration, argues that there is a difference in immunoreactivity and yet, in the 5/09 declaration argues that the immunoreactivity should remain the same. The data provided in the 7/19/07 declaration clearly show that there is a difference in the immunoreactivity and this made be attributed to the cis Tag.

Applicant also argues that the Licha et al reference does not state that its dyes have an increased fluorescence intensity. In col. 9, lines 25-28 the reference states that the cyanine dye showed a 1000 times greater fluorescence intensity as compared to a similarly dosed porphyrin".

Claims 15-37 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Neri et al Nature Biotechnology Vol. 15 p. 1271 (11/97) or Neri et al US 2003/0045681 (filed 5/11/98) in view of Viti et al Cancer Research vol. 59 p. 347

(1/99), applicant's admission in the sentence bridging pages 7-8 of the specification and Licha et al US 6083485 (filed 11/7/97) and Licha et al 6630570 (filed 4/12/99). The reasons for this rejection are of record in the paper mailed 6/22/06. The reasons for this rejection are of record in the paper mailed 11/27/07.

Applicant's arguments have been addressed above.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheela J. Huff whose telephone number is 571-272-0834. The examiner can normally be reached on Monday-Thursday 6am to 2pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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/Sheela J Huff/  
Primary Examiner  
Art Unit 1643

sjh